THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s):	M. Secretin
Appl. No.:	10/564,805
Conf. No.:	3416
Filed:	May 17, 2006
Title:	INFANT OR FOLLOW-ON FORMULA
Art Unit:	1782
Examiner:	Preston Smith
Docket No.:	3712036-00701

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated September 26, 2011 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit that the Examiner's Answer has failed to remedy the deficiencies with respect to the final Office Action dated January 19, 2011, as noted in Appellants' Appeal Brief filed on June 21, 2011, for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejection of pending Claims 1 and 5-21 be reversed.

II. THE REJECTION OF CLAIMS 1, 5-6, 9 AND 14-16 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully request that the Board reverse the rejection of Claims 1, 5-6, 9 and 14-16 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. In this regard, Appellants submit that the cited references fail to disclose or suggest each and every element of the present claims and that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

In the Examiner's Answer, the Examiner admits that "Carlson fails to explicitly teach arachidonic acid and docosahexaenoic acid both being present in the formula wherein the docosahexaenoic acid amount is 0.2-0.5%" but states that "Carlson does teach that the amount of docosahexaenoic acid may range from 0.25-35 mg" and that "Carlson teaches up to amounts over 4 times greater than 7 mg which would correspond to a much higher percentage than 0.14%." See, Examiner's Answer, page 15, lines 6-11. Based on these statements, the Examiner concludes that "one of ordinary skill in the art would have found it obvious to slightly increase the docosahexaenoic acid content to 7 mg (which results in 0.14%) to a slightly higher amount in order to boost the brain health boosting properties . . . of the formula." See, Examiner's Answer, page 15, lines 8-11. Appellants respectfully disagree.

As discussed in Appellants' Appeal Brief, besides failing to disclose or suggest the range of DHA content in the total fatty acids as claimed, *Carlson* does not even mention any percentages or the requirement of specific percentages of any specific fatty acids (e.g., ARA and DHA) in the total fatty acids in the lipid source according to the present claims. Indeed, even if *Carlson* discloses one embodiment of a fatty acid profile having ARA and DHA, it is not proper for the Examiner to extrapolate weight percents of ARA and DHA in different embodiments because total weight percents change based on the compositions in the lipid profile. Further, the Examiner acknowledges that "adjusting other components of the formula would effect the weight percentages of the individual components." See, Examiner's Answer, page 15, lines 19-21. Accordingly, Appellants respectfully submit that it would not have been obvious to increase the DHA levels to those of the present claims.

In the Examiner's Answer, the Examiner also states that "Applicant argues that the formula has the unexpected result of improving the gut function and lowering infant tolerance to milk" but "applicant has not specifically claimed these alleged unexpected results." See, Examiner's Answer, page 16, lines 1-3. In response, Appellants note that fundamental patent law includes no requirement that the results of administration of a composition be claimed. Thus, in contrast to the Examiner's statement, Appellants respectfully submit that the unexpected results of improving the gut function and lowering infant tolerance to milk need not be specifically claimed.

In the Examiner's Answer, in response to Appellants' unexpected results argument, the Examiner states that "taking [vitamin A and vitamin C] individually would be expected to produce the same effects as taking them in one formula." The Examiner further states that "Applicant has not discovered something unexpected by simply combining well known products with well known effects and then making a composite product having all the well known effects." See, Examiner's Answer, page 16, lines 9-14. Appellants respectfully disagree.

Appellants respectfully submit that, using the logic of the Examiner, no compositions would be patentable if the composition involved the combination of known ingredients. In contrast, Appellants respectfully submit that it is well known that certain ingredients can have canceling effects when paired with other ingredients and, conversely, certain ingredients can have synergistic effects when paired with other ingredients. Additionally, specific amounts of certain ingredients can have beneficial effects when ingested, while lesser or greater amounts of the same ingredients can have no effect, or even a detrimental effect when ingested. Accordingly, Appellants respectfully submit that it is improper for the Examiner to assume that simply combining ingredients would have the same effect as ingesting them separately.

Further, as discussed in Appellants' Appeal Brief, Appellants have surprisingly found that feeding infants the formula of the present claims generally results in the promotion of the immune defenses of the infant as has been demonstrated by an enhanced response to vaccinations and/or improved gut barrier function and lower levels of intolerance of cows' milk protein coupled with satisfactory physical development. These results are summarized in Examples 1 and 2 of the specification where infants that were fed a formula according to the present claims were compared to infants that were fed a similar formula but without probiotics. The results demonstrate that infants fed the formulas of the present claims generally display

strengthened immune defenses as demonstrated by an enhanced response to vaccinations and/or improved gut barrier function and lower levels of intolerance of cows' milk protein coupled with satisfactory physical development when compared with the control group. See, US 2007/0031537, Examples at paragraphs [0069] – [0077].

Appellants also submitted the methodology and trials detailing *in vitro* testing of compositions including ARA, DHA and *Lactobacillus paracasei* NCC 2461 (ST11). Generally, in the *in vitro* study, T84 cells were incubated overnight in serum free DMEM/F12 followed by a two hour pre-incubation with ST11 cells in the presence or absence of DHA/ARA. After the two hour pre-incubation, *Clostridium difficile* toxin A was added to the apical chamber. After an overnight incubation, transepithelial electrical resistances (TEER) were measured, and the protection of ingredients, alone and in combination, were measured. The results of the test indicate that a combination of a probiotic and DHA/ARA provides better results than either ingredient alone.

Because Appellants have shown that administering a probiotic and a source of lipid comprising ARA and DHA in the same formulas provides advantages over diets not providing this combination of ingredients, Appellants have shown that the claimed invention provides unexpected results over the prior art. Accordingly, the showing of unexpected results provides evidence that the claimed invention is not *prima facie* obvious in view of the cited references.

In the Examiner's Answer, the Examiner states that "[t]he Kankaanpää reference does not appear to establish that combining probiotics with PUFA's would be disadvantageous in the references cited by examiner. Just because Kankaanpää states that PUFA may influence the function of probiotics doesn't mean that the combination presented in the rejection wouldn't work." See, Examiner's Answer, page 17, lines 9-12. Appellants respectfully disagree with the Examiner's statements and respectfully submit that the Examiner appears to be manipulating the disclosures of the cited references and knowledge of the skilled artisan at the time of the invention in order to justify the present combination of references.

Kankaanpää expressly states that "[a]s polyunsaturated fatty acids (PUFA) possess antimicrobial properties, they may deter the action of probiotics." See, Kankaanpää, page 153 (emphasis added). Therefore, in contrast to the Examiner's statement, Kankaanpää does establish that combining probiotics with PUFA's would be disadvantageous. Of course, Kankaanpää does not expressly state that combining probiotics with PUFA's would be

disadvantageous in the combination of *Carlson* with *Halpin-Dohnalek*, however, Appellants respectfully submit that to require this type of specific knowledge from the skilled artisan at the time of the invention would be unreasonable absent a direct study comparing the combination of *Carlson* with *Halpin-Dohnalek*. Additionally, just as the Examiner states that "[j]ust because Kankaanpää states that PUFA may influence the function of probiotics doesn't mean that the combination presented in the rejection wouldn't work," Appellants respectfully submit that just because *Carlson* discloses a composition with ARA and DHA, and *Halpin-Dohnalek* discloses compositions with probiotics, doesn't mean that the presently claimed compositions and methods cannot provide unexpected results, or that the cited references are properly combinable. In fact, Appellants have demonstrated surprising results, as is discussed in detail herein above, as well as in Appellants' Appeal Brief.

In the Examiner's Answer, the Examiner states that "[i]n response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." See, Examiner's Answer, page 16, lines 17-20. In contrast, Appellants respectfully submit that, to the extent that the references are discussed individually, it is not to address the rejections as anticipation rejections under 35 U.S.C. §102(b), but rather to point out the deficiencies of the cited references. Accordingly, the cited references, even when taken as a whole, fail to recognize or even appreciate the advantages provided by the compositions and methods of the present claims, as discussed above.

The Examiner also states that "[i]n summary, applicant's invention is simply a 'formula' with carbohydrates, proteins, ARA, DHA, and a probiotic." See, Examiner's Answer, page 19, lines 1-2. However, Appellants respectfully disagree and submit that such a statement by the Examiner is an improper generalization of the present claims. In contrast, Appellants note that the present claims recite specific amounts of specific ingredients that provide unexpected and advantageous results. As discussed in the specification, the present claims result in a low EPA fish oil at a level that has been shown to achieve DHA levels in the various blood pools of formula-fed infants similar to those of breast-fed infants. Additionally, the specification demonstrates that infants fed the formulas of the present claims generally display strengthened immune defenses as demonstrated by an enhanced response to vaccinations and/or improved gut barrier function and lower levels of intolerance of cows' milk protein coupled with satisfactory

physical development when compared with the control group. See, US Publ. No. 2007/0031537, Examples at paragraphs [0069] – [0077].

Appellants respectfully submit that what the Examiner has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Appellants also submit that if it were proper for the Examiner to simply pick any claim element from any prior art reference to arrive at the present claims simply because the reference suggests the element, then every invention would effectively be rendered obvious. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Appellants respectfully submit that such a reason is not present in the instant case.

In sum, not only do the cited references fail to disclose or suggest each and every element of the present claims, but the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight.

Accordingly, Appellants respectfully submit that Claims 1, 5-6, 9 and 14-16 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance. As such, Appellants respectfully request that the obviousness rejection of Claims 1, 5-6, 9 and 14-16 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

III. THE REJECTIONS OF CLAIMS 7, 8 AND 10 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully request that the Board reverse the rejections of Claims 7, 8 and 10 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. In this regard, Appellants submit that the cited references fail to disclose or suggest each and every element of the present claims and that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

In the Examiner's Answer, the Examiner does not appear to address Appellants arguments with respect to dependent Claims 7, 8 and 10. Therefore, for at least the reasons set forth in Appellants' Appeal Brief and in Section II above, Appellants respectfully submit that the cited references are deficient with respect to dependent Claims 7, 8 and 10. Specifically, not

only do the cited references fail to disclose or suggest each and every element of the present claims, but the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight.

Accordingly, Appellants respectfully request that the obviousness rejections of Claims 7, 8 and 10 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

IV. THE REJECTION OF CLAIMS 11-13 AND 17-21 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully request that the Board reverse the rejection of Claims 11-13 and 17-21 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. In this regard, Appellants submit that the cited references fail to disclose or suggest each and every element of the present claims and that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

The Examiner's assertions with respect to the combination of *Carlson* in view of *Halpin-Dohnalek* are discussed herein above in Section II. In the Examiner's Answer, and with respect to *Kratky*, *Threonine* NPL, and *Bifidobacterial* NPL, the Examiner merely states that "Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein" and that since "Carlson doesn't teach sweet whey proteins[,] . . . Kratky was considered to remedy this lacking feature." See, Examiner's answer, page 18, lines 3-6. Accordingly, Appellants respectfully submit that *Kratky*, *Threonine* NPL, and *Bifidobacterial* NPL still fail to remedy the deficiencies of *Carlson* and *Halpin-Dohnalek*. Therefore, not only do the cited references fail to disclose or suggest each and every element of the present claims, but the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight.

Accordingly, Appellants respectfully submit that Claims 1 and 5-21 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance. As such, Appellants respectfully request that the obviousness rejections of Claims 1 and 5-21 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

V. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the obviousness rejections with respect to Claims 1 and 5-21.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00701 on the account statement.

Respectfully submitted,

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